

REMARKS

Applicant respectfully requests entry of the Amendment and reconsideration of the claims. Claim 12 has been amended to clarify the claimed subject matter. Applicant has added new claims 35-46. Support for new claims 35-46 can be found throughout the specification, including at paragraphs 43-44, 49, and 52-53, and the Examples for claim 35; at paragraph 61 for claim 36; at paragraphs 54 and 61 for claims 37 and 42; and at paragraph 46 for claims 38-41 and 43-46. No new matter has been added through the amendments or through the new claims. Applicant respectfully requests reconsideration and withdrawal of the pending rejections under 35 U.S.C. § 102(b) and § 103(a).

Application Data Sheet

The Examiner has stated that Applicant's submission of foreign priority documents from Canadian Patent application 2,452,032 filed September 9, 2005, is acknowledged but that the application number for this Canadian application was not provided in the Application Data Sheet filed on February 17, 2004. The Examiner has requested submission of an Application Data Sheet containing this information. Applicant submits a new Application Data Sheet containing this information.

Rejection Under 35 U.S.C. § 102(b)

The Examiner rejects claims 12 and 14 under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent Application Publication No. 2003/0148399 (Nemori et al.). To expedite prosecution, Applicant amended claim 12, thereby rendering this rejection moot. Applicant respectfully requests removal of this rejection.

Rejection Under 35 U.S.C. § 103(a)

The Examiner rejects claims 12 to 14 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent Application Publication No. 2002/0001582 (Charter *et al.*) taken with WO 96/06532 (Johansen). The Examiner contends that, at the time the invention was made, it would have been obvious to combine these two references to use protamine sulfate as the basic

protein (as taught by Johansen) in preparing a fungicidal composition comprising one or more active ingredients including ovotransferrin and EDTA (as taught by Charter *et al.*). Applicant respectfully traverses.

The Examiner states that Charter *et al.* disclose a fungicidal composition comprising one or more “active ingredients” which is selected from a group of avidin, lysozyme, ovotransferrin, chicken immunoglobulins, chitosan, polylysine, protamine, nisin, EDTA, rosemary, cinnemaldehyde, allicin and eugenol. The Examiner combines this with WO 96/06532, which discloses an antimicrobial composition comprising a basic protein in combination with a cell wall degrading enzyme or an oxidoreductase, where either protamine or protamine sulfate can be used as the basic protein.

WO 96/06532 discloses a composition capable of killing microbial cells or inhibiting growth of microbial cells, i.e., a bacteriocidal, bacteriostatic, fungicidal and/or fungistatic composition, for use as a cleaning or detergent composition, and methods of killing microbial cells present on a hard surface, on skin, or in laundry, and for preserving food products, cosmetics, etc. (see abstract). WO 96/06532 also discloses natural alternatives for antimicrobial agents used for preserving foods, as disinfecting and as antimicrobial ingredients in detergent and cleaning compositions (see background of the invention). In contrast, Charter *et al.* disclose the inhibition of growth of fungi or protists on plants and plant tissues. Charter *et al.* disclose an agricultural fungicidal agent – a method for treating plants, plant tissues, and seeds that are already infected with the fungi or protist pathogens.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in general knowledge to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference(s) must teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); MPEP 2143.

Nonanalogous Art and Expectation of Success. Applicant respectfully asserts that U.S. Patent Application Pub. No. 2002/0001582 (Charter *et al.*) is not analogous art to the instant

claims.

The determination that a reference is from a nonanalogous art is therefore two-fold. First, we decide if the reference is within the field of the inventor's endeavor. If it is not, we proceed to determine whether the reference is reasonably pertinent to the particular problem with which the inventor was involved. *In re Deminski*, 796 F.2d 436, 442 (Fed. Cir. 1986); *In re Clay*, 966 F.2d 656, 658-659 (Fed. Cir. 1992).

The '582 publication solely discloses a composition for inhibiting fungi and protists. The instant inventor's endeavor is compositions that inhibit bacteria in a biofilm. Applicant further asserts that antifungal agents are not reasonably pertinent to antibacterial agents due to the complex differences between the two microorganisms. All living organisms are divided into two basic cellular types--eukaryotes (which includes fungi, protists, mammals, etc.) and prokaryotes (which includes bacteria). This classification is based on fundamental differences in cell structure. Due to the differences in cell structure, there is no expectation that an antimicrobial that works against fungi would inhibit bacteria in a biofilm. Therefore, antifungal agents are not analogous to antibacterial agents and there is not expectation of success for an antifungal agent to inhibit a bacterial biofilm.

Motivation to combine. Applicant respectfully asserts that there is no motivation to combine these two references. The Johansen reference is directed to a completely different solution to a completely different problem than the Charter et al. reference. Whereas Charter et al. are concerned with inhibition of already-existing fungi on plants and plant tissues, Johansen is developing a detergent or cleaning composition. There is no motivation in either reference to combine the two references. In addition, Charter et al. do not specifically teach the use of protamine sulfate in the composition. Johansen only discloses the use of protamine or protamine sulfate in combination with a cell wall degrading enzyme or an oxidoreductase. Thus, even if the two references were combined, combining the teachings of Johansen with Charter *et al.* does not motivate or teach one to combine ovotransferrin with protamine sulfate. Thus, Applicant submits that since there is no suggestion or motivation to combine the two pieces of prior art cited.

In any event, the mere fact that references can be combined does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re*

Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Since the two prior art references are directed to different solutions to different problems (inhibition of growth of fungi on plants vs. cleaning or detergent compositions), the prior art does not suggest the desirability of the combination.

Applicant submits that, even if one were to combine Charter et al. and Johansen, neither of these two publications suggest the claimed compositions specifically, since Charter et al. list a long laundry list of possible agents. Given the long list of possible agents in Charter et al., combined with Johansen's disclosure of the use of protamine or protamine sulfate in combination with a cell wall degrading enzyme or an oxidoreductase, Applicant respectfully asserts that the Examiner is using hindsight reconstruction to find the present claims obvious.

Unexpected results. The instant inventor is the first to show an unexpected enhanced effect for inhibiting bacterial biofilm on devices by the use of the selected claimed compositions (see, for example, figures 10 and 12). There is absolutely nothing in Charter *et al.* nor Johansen that would suggest an enhanced effect for the combination of ovotransferrin, protamine sulfate, and EDTA, or ovotransferrin and protamine sulfate, or ovotransferrin and EDTA, over any of these compounds alone. Applicant submits that the unexpectedly enhanced results discovered and taught in the present specification are not rendered obvious by Charter *et al.* in combination with Johansen.

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

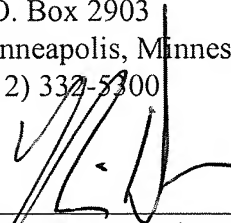
Summary

In view of the above amendments and remarks Applicant respectfully requests a Notice of Allowance. If the Examiner believes that a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 332-5300

Date: April 10, 2006



Brian R. Dorn, Ph.D.
Reg. No. 57,395
BRD:RAD:sab

23552

PATENT TRADEMARK OFFICE